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Immunization Products to Prevent Severe RSV Illness in Infants

Respiratory syncytial virus (RSV) is common, easily spread, and a major cause of lower respiratory tract infections in infants and young children seasonally (usually late fall to early spring). Immunization products are available to protect infants and children in the short term against the severe effects of RSV. Premature infants and infants with certain medical conditions (e.g., chronic lung disease, chronic cardiac disease, compromised immune systems, neuromuscular disorders) are at higher risk of severe RSV illness.[1] However, full-term infants with no underlying comorbidities make up the largest group of infants affected by severe RSV disease.[1,2]

Health Canada Approved Products

Monoclonal Antibodies
(administered directly to infants/young children)

Synagis® (palivizumab) is a human monoclonal antibody approved for the prevention of severe lower respiratory tract disease caused by RSV in pediatric patients at high risk of RSV disease.[3] Palivizumab requires monthly doses throughout the RSV season (4 or 5 doses).[1,3]

- Date approved for use in Canada: May 2002[4]

Beyfortus® (nirsevimab) is a human monoclonal antibody approved for the prevention of RSV lower respiratory tract disease in neonates and infants during their first RSV season and in children under 24 months of age with specific medical conditions through their second RSV season.[5] Nirsevimab is longer acting than palivizumab and only requires one dose per RSV season. Nirsevimab is potentially more effective than palivizumab at reducing RSV disease requiring medical attention, hospitalization, and ICU admission.[2]

- Date approved for use in Canada: April 2023[6]

Vaccine
(administered to pregnant individuals from 32 through 36 weeks of gestation)

Abrysvo™ (RSVpreF) is indicated for use in pregnant individuals from 32 through 36 weeks' gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by RSV in infants from birth through 6 months of age.[7]

- Date approved for use in Canada: December 2023[8]

National Advisory Committee on Immunization (NACI) Recommendations[2]

- Beyfortus® (nirsevimab) is preferred over Synagis® (palivizumab) and maternal Abrysvo™ (RSVpreF).
- NACI recommends Beyfortus® (nirsevimab) for all infants but acknowledges it will take time to build universal programs; when appropriate, introduction of the agent can be phased in through prioritization of higher risk infants.
- Immunization of pregnant individuals with Abrysvo™ (RSVpreF) may be considered as an individual informed decision.

Saskatchewan RSV Program[9]

- The Saskatchewan RSV Program coordinates RSV prophylaxis with **Synagis®** (palivizumab) for eligible infants and children who meet criteria (not available for purchase in pharmacies).
- Coordinators in Regina, Saskatoon, and Prince Albert identify all preterm infants born in the province who qualify based on hospital admission. The program also obtains referrals from cardiology, respirology, and other specialties that have infants who may qualify.
- Not all infants or young children are eligible for **Synagis®** (palivizumab). It is offered only to infants and children who are likely to benefit the most from prophylaxis.
- Certain premature infants and infants with specific chronic health conditions are eligible.
- Prophylaxis may be considered for other children on a case-by-case basis.
- According to a representative of the program, **Beyfortus®** (nirsevimab) **will not be available for the 2024-2025 RSV season in Saskatchewan** (email communication, June 13, 2024).
- Contact the RSV program in your area for more information:
  - North: 306.765.6328, RSVNorth@saskhealthauthority.ca
  - Central: 306.655.0679, RSVCentral@saskhealthauthority.ca
  - South: 306.766.4574, RSVSouth@saskhealthauthority.ca

RSV Immunization Resources

Immunize.ca:
Respiratory Syncytial Virus (RSV)

Moms & Kids Health Saskatchewan:
Respiratory Syncytial Virus Program
RSV Information to Help Your Baby

Vaccines in Pregnancy Canada:
Respiratory Syncytial Virus (RSV) Vaccine

See next page for immunization Product Considerations

Immunization Product Considerations

Beyfortus® (nirsevimab)

- Not yet available in Saskatchewan.

Synagis® (palivizumab)

- Available and provincially funded for eligible infants and children for the 2024-2025 RSV season.[9]
- Requires monthly infant injections (up to 5) before or during RSV season.[1]
- May take up to two days after administration to reach protective levels.[10]
- Reported to reduce hospitalizations from severe RSV illness by 40 to 80% compared to no infant immunization.[11]
- Side effects are uncommon.[3]

Saskatchewan pharmacists are not authorized to prescribe RSV vaccine for pregnant individuals.

Pregnant individuals are encouraged to discuss infant RSV prevention with their pregnancy care providers.

Abrysvo™ (RSVpreF)

- Provides immediate protection through maternal antibody transfer if provided at least 14 days before birth.[1]
  - Protection may be reduced if fewer antibodies are produced (e.g., vaccine recipient is immunocompromised, or infant is born within 14 days of vaccination).[1]
- Maternal immunization is reported to reduce infant RSV-associated hospital admission by 57% compared to no vaccination.[1]
- Effective during the first few months of life when infants are at the highest risk of severe RSV illness and not expected to provide protection after four to five months.[2]
- Available for purchase but not provincially funded for the 2024-2025 RSV season.[12]
- Safety and efficacy with certain high-risk pregnancies is unknown.[7]
- There was no difference in preterm birth rates between those who received vaccine or placebo in studies in high-income countries like Canada. Studies outside of Canada showed a potential risk of preterm birth when given between 24 to 36 weeks of pregnancy. It is not clear if the vaccine caused these events and research is ongoing. In Canada, around 8% of all births occur before term. The rates in the studies were lower than what is expected in the general population. Vaccination between 32 and 36 weeks of pregnancy reduces this potential risk.[1,2,13]

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